




ATTORNEY'S DOCKET NUMBER: 0492479-0018 (MGH 1661.0)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Scadden *et al.*  
Serial No.: 09/803,687  
Filed: March 9, 2001  
For: *p27 and p21 in Gene Therapies*

Examiner: Katcheves, K.  
Group Art Unit: 1636

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

<b>Certificate of Mailing</b>	
I certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.	
<u>April 3, 2006</u> Date	<u></u> Signature
<u>Heather A. Mariacher</u> Name of Person Signing	

Sir:

**STATEMENT UNDER 37 C.F.R. §§ 1.56, 1.97, AND 1.98**

Pursuant to the duty of disclosure under 37 C.F.R §§ 1.56, 1.97 and 1.98, Applicant requests consideration of this Information Disclosure Statement.

Type of Statement

The present Information Disclosure Statement is:

- ☐ An *original* Information Disclosure Statement; or
- ☒ A *supplemental* Information Disclosure Statement.

Compliance with 37 CFR § 1.97

The present Information Disclosure Statement is being filed:

- ☐ Pursuant to 37 CFR § 1.97(b); no fee or certification is required:
  - ☐ Within three months of the filing date of a national application other than a continued prosecution application under § 1.53(d);
  - ☐ Within three months of the date of entry of the national stage as set forth in § 1.491 in an international application;
  - ☐ Before the mailing of a first Office action on the merits; or
  - ☐ Before the mailing of a first Office action after the filing of a request for continued examination under § 1.114.
- ☒ Pursuant to 37 CFR § 1.97(c) after the dates listed above but before the mailing date of any of a final action under § 1.113, a notice of allowance under § 1.311, or an action that otherwise closes prosecution in the application; Applicant hereby *either*:
  - ☐ Certifies that *either*:
    - ☐ each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or
    - ☒ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the

information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement; or

☐ Includes herewith the fee set forth in § 1.17(p),

☐ Pursuant to 37 CFR § 1.97(d), after the mailing date of any final action under § 1.113, a notice of allowance under § 1.311, or an action that otherwise closes prosecution in the application; Applicant hereby *both*:

☐ Certifies that *either*:

☐ each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement; and

☐ Includes herewith the fee set forth in § 1.17(p).

## Content of the Information Disclosure Statement

Applicant hereby makes of record in the above-identified application the reference(s) listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

Applicant includes copies of references as indicated below:

- ☒ A copy of each cited reference not indicated with an asterisk is included;
- ☐ Copies of references indicated with an asterisk on the attached form PTO-1449 are not included pursuant to 37 CFR § 1.98(d) because they were previously provided to the United States Patent Office in an Information Disclosure Statement that complies with 37 CFR § 1.98(a)-(c) and was submitted in the following patent application that is relied upon in the present case for an earlier effective filing date under 35 USC § 120:

Serial Number	Filing Date	Status

- ☐ Copies of English translations of one or more non-English references are included.

Applicant hereby makes the following additional information of record in the above-identified application:

Applicant certifies that the Information Disclosure Statement *either*:

- ☐ Does not contain non-English language citations;
- ☐ Includes one or more translations of a non-English citation; or
- ☐ Does contain non-English language citations, of which the following is a concise explanation:

## Remarks

The submission of this Information Disclosure Statement should not be construed as a representation that a search has been made.

The submission of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in § 1.56(b) .

The submission of this Information Disclosure Statement shall not be construed as a representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 USC § 102.


It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited patent(s) and publication(s) has (have) been fully considered by the Patent and Trademark Office during the examination of this application; and
3. The citations for the patent(s) and publication(s) be printed on any patent which issues from this application.

Notwithstanding any statements by Applicants, the Examiner is urged to form his or her own conclusions regarding the relevance of the cited reference(s).

Respectfully submitted,

Dated: April 3, 2006

A handwritten signature in black ink, appearing to read 'C. Hunter Baker', is written over a horizontal line.

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<b>Form PTO-1449</b> (REV. 8-83)	U.S. Department of Commerce Patent and Trademark Office	Atty. Docket: 0492479-0018 (MGH 1661.0)	In re Application No. 09/803,687
		Applicant: Scadden <i>et al.</i>	
<b>INFORMATION DISCLOSURE STATEMENT</b> (Use several sheets if necessary)		Filing Date: March 9, 2001	Group: 1636

U.S. PATENT DOCUMENTS					
Examiner's Initials	U.S. Patent No.	Applicant	Issue Date	Class	Subclass

U.S. PATENT APPLICATIONS					
Examiner's Initials:	Serial Number:	Applicant:	Filing Date:	Group:	Art Unit:

FOREIGN PATENT DOCUMENTS					
Examiner's Initials	Document No.	Country	Date	Translation	
				Yes	No

OTHER DOCUMENTS	
Examiner's Initials	Citation (Including Author, Title, Date, Pertinent Pages, Etc.)
	Clarke, "Isolation and characterization of human mammary stem cells," <i>Cell Prolif.</i> <b>38</b> : 375-386, 2005.
	Kippin <i>et al.</i> , "p21 loss compromises the relative quiescence of forebrain stem cell proliferation leading to exhaustion of their proliferation capacity," <i>Genes &amp; Development</i> , <b>19</b> : 756-767, 2005.
	Qiu <i>et al.</i> , "Regenerative Response in Ischemic Brain Restricted by p21 <sup>cip1/waf1</sup> ," <i>J. Exp. Med.</i> , <b>199</b> (7): 937-945, April 15, 2004.
	Topley, <i>et al.</i> , "p21 <sup>WAF1/cip1</sup> functions as a suppressor of malignant skin tumor formation and a determinant of keratinocyte stem-cell potential," <i>Proc. Natl. Acad. Sci. USA</i> , <b>96</b> : 9089-9094, August 1999.
EXAMINER	DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.